

Appl. No. 10/030,735
Amdt. dated November 11, 2005
Amendment and Reply under 37 CFR 1.116 Expedited
Procedure Examining Group 1644

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REMARKS/ARGUMENTS

Page 16 of the Specification has been restored to the text as originally filed in light of helpful suggestions from Quality Assurance Specialist (QAS) Bonnie Eyler as described further below. Briefly, the text presents Formula (I) followed by the detailed and precise description of positions in the formula in Markush type language as originally presented.

Claims 1, 2, 5, 8, 9, and 46 have been revised to utilize the same formula I as found on page 16 of the specification and in the claims as originally filed. The formula is followed by the same type of detailed and precise description of the positions in the formula in the same Markush type language as found on page 16. More specifically, and in claim 1, position X_1 is selected from the group consisting of N, Q, and D; position X_2 is V; position X_3 is R; and position X_4 is L. The previous possibility of position X_4 as F has been moved to claim 5 (which previously depended from claim 1) so that claim 5 now contains all other features of previous claim 1. No other feature of claim 1 has been changed except as discussed below. The scope of claim 1 with respect to positions X_1 through X_4 as previously presented is now identically found in a combination of claims 1 and 5. No loss of claim scope was intended or believed to have occurred.

Claims 1 and 46 have also been revised to no longer be directed to "partial" retro-inverso sequences. A corresponding cancellation of claim 7 is also made. These changes are not made in acquiescence to any position set forth in the Office Action mailed July 12, 2005 but rather to reduce the number of issues remaining in the instant application. Applicants expressly reserve the right to pursue the "partial" retro-inverso subject matter in a continuing application.

No new matter has been introduced, and entry of the above revisions to the specification and claims is respectfully requested.

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In-person Interview of October 20, 2005

Applicants thank Quality Assurance Specialist (QAS) Bonnie Eyler, Supervisory Patent Examiner (SPE) Christina Chan, and Examiner Maher Haddad for the courtesy of an in-person interview with the undersigned on October 20, 2005. The focus of the interview was the continuing issue of alleged "new matter" in the claims after they were revised to be directed to the subject matter that was elected by Applicants and searched by Examiner Haddad. The undersigned pointed out that the claim revisions were to encompass specific species within the description of formula (I) in the instant application as originally filed.

The undersigned also pointed out that Applicants revised the specification and claims in the response filed June 24, 2005 to point out how formula (I) as originally filed disclosed a simple genus that was defined by 96, and only 96, discrete species. Given this small genus and finite number of species, the claim revisions to encompass specific species from within the 96 could not constitute "new matter". Moreover, the absence of "new matter" is supported by the fact that the claim revisions were made to conform the claims to the original Restriction Requirement in the instant application. Because the Restriction limited the search and examination to a few species, how can the few species found to be allowable subject matter be granted as a patent claim if the claims cannot be revised to encompass those searched and allowable species?

The undersigned also pointed out that the position taken by the Examiners was based upon *In re Smith*¹ while Applicants had already pointed to *In re Johnson*² as a more relevant decision which fully supports Applicants' position. Moreover, and in addition to the guidance from *Johnson*, Applicants could rely on the Federal Circuit decision in *Union Oil Co. of California v. Atlantic Richfield Co.*³

¹ 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

² 194 USPQ 187 (CCPA 1977).

³ 54 USPQ2d 1227 (Fed. Cir. 2000).

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QAS Eyler helpfully pointed out that she and the Examiners had reviewed the instant application and situation with consultation from OPLA (Office of Patent Legal Administration) and were trying to balance the *Smith* and *Johnson* decisions. She indicated that if the specification and claims were restored to the Markush-type language as originally presented, and then accompanying by a more detailed comparison to *Johnson*, the similarities to *Smith* would likely be reduced in relevance in comparison to *Johnson*. She further indicated that they were willing to review such revised claims and arguments as well as present them to OPLA for consultation. The undersigned agreed to consider such an approach along with the possibility of including arguments based on *Union Oil*.

Further discussion of the *Smith* and *Johnson* decisions is provided below.

Withdrawn Claims and Rejoinder

Claims 20, 21, 23-26, and 28-30 were withdrawn from consideration. Claims 20, 21, 23-26, and 28-30 remain directed to methods comprising the use of a peptide according to claim 1 (claims 20, 21, 23-26, and 28-29) or claim 2 (claim 30). As such, they have all the limitations of elected claims 1 and 2 and are subject to rejoinder as set forth at MPEP 821.04. Applicants respectfully ask that claims 20, 21, 23-26, and 28-30 be rejoined and allowed along with claims 1 and 2.

Furthermore, Applicants thank the Examiner for suggesting the use of dual status identifiers. As the claims are not further revised above, the single status "withdrawn" identifier has been used for claims 20, 21, 23-26, and 28-30.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3, 5, 7, 13, 14 and 46-52 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to reasonably provide enablement for "partial" retro-inverso peptides as recited in claims 1 and 46.

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Similarly, claims 1-3, 5, 7, 13, 14 and 46-52 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an adequate written description for "partial" retro-inverso peptides as recited in claims 1 and 46.

Claims 1 and 46 have been revised above to obviate the basis of this rejection without acquiescence to the instant rejections and to reduce the number of issues in the instant application. Applicants respectfully submit that these two rejections may be properly withdrawn.

Objections under 35 U.S.C. § 132

The specification was objected to as allegedly containing new matter in light of the revisions filed June 24, 2005. Applicants have carefully reviewed the statement of the objection and respectfully traverse as no *prima facie* case of "new matter" in the specification has been presented.

Simply put, Applicants continue to believe that the simple "writing out" of the 96 possible sequences as encompassed by formula (I) and the Markush-type language (in the application as originally filed) **cannot** be held to be "new matter" without reliance on an improper *in ipsius verbis* test. Given that the sole basis of the objection is the allegation that "the specification and claims as originally filed have no support for the new replacement of such sequences", Applicants believe that an improper *in ipsius verbis* test has been applied and so no *prima facie* case is present.

Nevertheless, and in light of the helpful suggestion from QAS Eyler as described above, Applicants have restored the language in the specification to be the original as filed. Accordingly, this objection maybe properly withdrawn.

Applicants further note that with the restoration of language in the specification, no further compliance with the Sequence Rules at 37 CFR § 1.825 *et seq.* is necessary.

"New Matter" Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3, 7-9, and 13-14 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing "new matter" not described in the specification as filed. Specifically, the

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statement asserts that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection."

Applicants have carefully reviewed this rejection in light of the in-person interview of October 20, 2005 and the helpful suggestions by QAS Eyler. In light of the review, Applicants respectfully, but emphatically, maintain the position that no *prima facie* case of an inadequate written description due to "new matter" is present against the above revised claims.

Applicants understand that a discussion of the pending claims and the *Smith* and *Johnson* decisions may be helpful to advance prosecution in the instant application because the instant rejection appears to lack adequate consideration of *Johnson*, which expressly distinguished *Smith*.

As an initial matter, and to aid in the consideration of *Johnson*, the claims have been restored to the use of formula (I) and the Markush-type language as found in the specification and claims on initial filing. This was based in part upon the helpful suggestion from QAS Eyler and the *Johnson* decision.

As Applicants have previously noted, the Examiners have relied upon the *Smith* decision⁴ with the assertion that a "subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads." A review of *Smith* shows that the court's holding was made in rejecting appellant's argument that "disclosure of a genus and a species of a subgenus is a sufficient description of the subgenus".⁵ But as Applicants have previously pointed out, the instant application does not rely upon this rejected appellant argument. To the contrary, the instant application and claims differ significantly from *Smith*.

⁴ See 173 USPQ 679 at 683. The court in *Smith* also states that "[p]recisely how close the description must come to comply with § 112 must be left to case-by-case development." This indicates that *Smith* can only be applied narrowly based on its precise facts and arguments.

⁵ *Id.*

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Specifically, and contrary to the statement of the rejection, the instantly revised claims are directed to peptides with specific sequences that are each disclosed as part of a genus in the instant application. Thus the claims may be viewed as directed to a "subgenus" of the disclosed genus where the "subgenus" is defined by the species fully disclosed as part of the genus. Alternatively, the claims may be viewed as directed to multiple individual species, each of which are disclosed such that the claims encompass more than one disclosed species (in the case of revised claims 1, 5 and 8 above) or a single "species" (in the case of claims 46 and 53). Therefore, and very different from *Smith*, the instant application is not one where claims are redirected to a subgenus based on disclosure of only a genus and one species of the subgenus.

To the contrary, the instant application is more appropriately viewed as one where the specification discloses a genus composed of a plurality of specific, and disclosed, species. Those species are disclosed in part by using Markush-type language to specify the sequence of each species. This is readily apparent in a simple comparison of the claims to the formula on page 16 of the specification. Both the claims and the specification recite formula (I) with Markush-type language, where portions of the claims recite the abbreviated form of the Markush-type language (e.g. X₂ is ...) when the Markush grouping is reduced to a single member of the group.

The revised claims simply reflect Applicants' revision of claims directed to a genus by subtracting member species from the Markush grouping used to define the genus. The resulting claims continue to encompass amino acid polymers that contain a peptide backbone where the particular amino acid residues define the side chains that are attached to the peptide backbone.

Thus the instant claims are analogous to the claims, directed to linear thermoplastic polymers, at issue in *Johnson*. As the *Johnson* court found, the application disclosed polymers containing both an E moiety, which was broadly defined and then exemplified by 50 specific examples, and an E' moiety, which was defined as a broad class of

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possibilities.⁶ Therefore, the large genus of polymers was based in part on combinations of the E and E' moieties.

Despite the large scope of the disclosure in *Johnson*, the Court of Customs and Patent Appeals (CCPA) held that claims to a subgenus of the possible polymers were adequately disclosed and raised no issue of "artificial subgenus" or "new matter". Specifically, the CCPA affirmed claims to polymers wherein "[t]wo of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is *claiming less* than the full scope of his disclosure" (emphasis in the original).⁷

In accepting the claims to a subgenus of the disclosure, the CCPA set forth an often quoted directive to avoid the

"triumph of form over substance [by] substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed"⁸

The CCPA's often quoted directive, which should be followed in the instant application, is simple and direct:

"It is for the inventor to decide what *bounds* of protection he will seek." (emphasis in the original)⁹

So in accordance with the directive, and with a comparison of the facts in *Johnson* to the instant application, it is readily apparent that the number of Johnson's possible polymers was much greater than the number of sequences in formula (I) of the instant application. The instant disclosure is much more specific and detailed as to the possibilities for the X₁ to X₄ positions in formula (I), which are expressly identified as being one of 4, 3, 2, and 4 options,

⁶ See 194 USPQ 187 at 190-1.

⁷ See 194 USPQ 187 at 195.

⁸ See 194 USPQ 187 at 196, quoting from *In re Saunders*, 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA 1971).

⁹ See 194 USPQ 187 at 196.

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So in accordance with the directive, and with a comparison of the facts in *Johnson* to the instant application, it is readily apparent that the number of *Johnson*'s possible polymers was much greater than the number of sequences in formula (I) of the instant application. The instant disclosure is much more specific and detailed as to the possibilities for the X₁ to X₄ positions in formula (I), which are expressly identified as being one of 4, 3, 2, and 4 options,

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respectively. This leads to the total of 96 possible species of sequence. Like *Johnson*, Applicants are now "claiming less than" the full scope of those 96 disclosed possibilities. If the instant rejection is to be maintained, Applicants respectfully ask for specific reasons why this close analogy to *Johnson* is insufficient to render *Smith* inapplicable.

Moreover, Applicants point out that the CCPA expressly distinguished *Smith* as follows:

In *Smith* the applicant sought the benefit of his prior application for a broadened generic claim, replacing the claim limitation "at least 12 carbon atoms" with a new limitation calling specifically for 8 to 36 carbon atoms, where there was no disclosure of either the range itself or of a sufficient number of species to establish entitlement to the claimed range.¹⁰

This situation in *Smith* is in sharp contrast to the instant application, where a genus composed of 96 specific species is fully disclosed and enabled such that there is no issue of each species being disclosed (as supported by the Examiners' position in setting forth the Restriction Requirement) and enabled (as there is no issue of non-enablement) and free of prior art (as there is no prior art based rejection). Thus to assert that Applicants have somehow failed to disclose, and so have failed to satisfy the requirements of 35 U.S.C. § 112, first paragraph, is simply contrary to the CCPA's guidance in *Johnson*.

As the CCPA stated in *Johnson*, "[a]ll that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count."¹¹ Similarly, and in the instant application, all that has happened is that Applicants have revised the claims to focus the bounds of protection on particular species rather than the original genus.

Moreover, and to the extent that the Federal Circuit has apparently adopted the CCPA's reasoning in *Johnson*, Applicants point out that in *Union Oil*, the Federal Circuit held that no "new matter", and so an adequate written description, was present to support claims directed to embodiments not distinctly disclosed in the written disclosure. Specifically, gasoline

¹⁰ *Id.*

¹¹ *Id.*

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formulations based on the picking and choosing among four to six, perhaps as many as eight, different types of fuel characteristics to arrive at a claimed combination were held as supported by an adequate written disclosure. The fuel characteristics include those that are defined functionally. For example in claim 117 of the patent at issue in *Union Oil*, the characteristics were

- 1) "a Reid Vapor pressure no greater than 7.0 psi";
- 2) "a 50% D-86 distillation point no greater than 200°F";
- 3) "a 90% D-86 distillation point no greater than 300°F";
- 4) "a paraffin content greater than 85 volume percent";
- 5) "an olefin content less than 4 volume percent"; and
- 6) "wherein the maximum 10% distillation point is 158°F (70°C.)"¹²

In arriving at its holding, the Federal Circuit expressly noted that the patent at issue "unmistakably informs the skilled [gasoline] refiners to increase or decrease the various components to arrive at preferred combinations."¹³ This is analogous to the instant application, where formula (I), as presented on page 16, unmistakably directs the skilled artisan to select among 4 specific possibilities for X₁; 3 specific possibilities for X₂; 2 specific possibilities for X₃; and 4 specific possibilities for X₄. The pending claims are even more specific, only directing the skilled artisan to select among 3 possibilities for X₁ in claims 1 and 8, and 2 possibilities for X₁ in claim 5.

So in contrast to *Union Oil*, the instant specification only has 4 or fewer, and the claims have 3 or fewer, possibilities for each of X₁ to X₄. This is in contrast to the enormous number of possibilities encompassed by the functionally defined fuel characteristics in *Union Oil*.

¹² 54 USPQ2d 1227 at 1228, quoting from U.S. Patent 5,288,393, column 24, lines 24-27.

¹³ 54 USPQ2d 1227 at 1234.

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In light of the above comparison, Applicants respectfully submit that like the claims of the patent in *Union Oil*, the instant claims must also be supported by an adequate written description and so no "new matter" is present. If the instant rejection is to be maintained in spite of the above comparison, Applicants respectfully ask for specific reasons why the holding in *Union Oil* is inapplicable.

As shown by the foregoing, Applicants respectfully submit that no *prima facie* case of "new matter" is present, and this rejection may be properly withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6151.

Respectfully submitted,



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